

**Advisory Action  
Before the Filing of an Appeal Brief**

<b>Application No.</b> 10/771,388	<b>Applicant(s)</b> ZERBE ET AL.
<b>Examiner</b> LEZAH W. ROBERTS	<b>Art Unit</b> 1612

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 02 July 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
 Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☒ Applicant's reply has overcome the following rejection(s): 103 rejection of claim 57 over Majeti in view of Stanley et al.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_  
 Claim(s) objected to: 57  
 Claim(s) rejected: 10-29,31,33-40, 52-56  
 Claim(s) withdrawn from consideration: 41-51

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
 13. ☒ Other: PTO-892.

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612

/Lezah W Roberts/  
Examiner, Art Unit 1612

Continuation of 3. NOTE: Applicant has proposed to amend claim 37 to recite the limitation "and wherein the total concentration of surfactants is in the range of 0.1 to 5%-wt". This limitation was not previously considered in regard to the compositions of claim 37, and further analysis would be required to determine whether "and wherein the total concentration of surfactants is in the range of 0.1 to 5%-wt" would have been obvious. Additionally a further search would also have to be made to determine the state of the art with regard to this issue.

Continuation of 11. does NOT place the application in condition for allowance because: In regard to Story et al., the Examiner disagrees and submits that the reference discloses that micelles are formed by surfactants. Surfactants have two distinct regions in their chemical structure, termed hydrophilic (water-liking) and hydrophobic (water-hating) regions. Micelles are aggregates in which the surfactant molecules are generally arranged in a spheroidal structure with the hydrophobic region at the core shielded, in an aqueous solution, from the water by a mantle of outer hydrophilic regions. It is concluded that micelle formation occurs in water with or without a drug present. The surfactant solubilizes the drug and therefore the drug takes on the form or attributes of the vehicle (the surfactant) and forms into micelles. The reference also discloses "However, there may be cases where a mixture of two or more surfactants provides an improved degree of solubilization over either surfactant used alone". Although the reference teaches formulations comprising NSAIDs, the primary reference teaches the incorporation of surfactants in the film compositions. Further surfactants are known in the art as solubilizers in compositions where active agents includes nicotine (Mezaache et al., US 6,165,512), and therefore the teaching of a mixed solvent system in Story et al. may be applied to the films comprising nicotine.

Although Majeti does not disclose hydroxypropylmethyl cellulose, it does disclose hydroxypropyl cellulose which has been disclosed in the art as equivalents. Further Majeti discloses cellulose derivatives are suitable for the compositions. In regards to the time of dissolution, although the reference is silent in regard to this property, it discloses an example of a single layer composition comprising two water soluble polymers. It is reasonable to conclude these films dissolve similar to those recited in the claims or have rapid dissolution, especially considering the claims do not recite a specific time of dissolution. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See MPEP 2144, IV. Applicant asserts that employing nicotine salts rather than nicotine base suppress the unpleasant odor of nicotine. Nicotine salt is more stable than nicotine base, and therefore there is motivation to use the salt in place of the base. In regards to the flavorings, Majeti discloses flavorings are suitable in the compositions and Arachaya discloses tartaric acid is a flavoring and therefore it is reasonable to use flavorings known in the art. Majeti discloses using sorbitol and menthol which suggest using these components in the compositions.

Applicant's arguments that the newly amended claim 37 is patentable over the prior art references are moot at this time due to non-entry of the proposed amendment.

In regards to the rejection over Majeti in view of Stanley et al and Dam, caramel has a brown color. It is reasonable to conclude that when added to a solution that that solution would take on some brown characteristic. Further caramel is disclosed as a color additive and therefore should act as a coloring agent no matter the thickness of the compositions. It is also reasonable to conclude that if it colors a thick composition that it will color one that is much thinner.